

CERTIFICATE OF ANALYSIS

(Certificate No. KMA078017-01)

Release Date: 23/01/2025

Re-test Date: 22/01/2028

Albuterol Impurity G

Identification

Chemical Name :

2-[Benzyl(1,1-dimethylethyl)amino]-1-[4-hydroxy-3-(hydroxymethyl)phenyl]ethanone (as per EP)

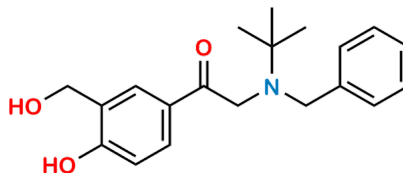
Alt. Name : Salbutamol BP Impurity G ; N-Benzyl
Salbutamone HCl ; Benzylsalbutamon

CAT No. : KMA078017

CAS No. : 64092-10-0

Molecular Formula : C₂₀H₂₅NO₃

Molecular Weight : 327.4



Analytical Information

Batch No. : A078017-091-174

Solubility : Acetonitrile

Description : Light Yellow Hygroscopic Solid

Mass : Confirm

HPLC Purity : 97.72 %

IR : Confirm

Weight Loss By TGA : 1.09 %

¹H NMR : Confirm

% Potency : 96.65 %

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition : Product is stable to be Shipped at Room Temperature

% Potency = [100 - 1.09(Weight Loss By TGA)] x [97.72(HPLC Purity)]/100 = 96.65 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		27/01/2025
Reviewed & Approved By	Quality Control	Jatin Patel		27/01/2025

Attachments : COA, HPLC, MASS, ¹HNMR, IR and TGA